

Variable	Mean	SD	Min	Max
Age	38.5	12.5	18	65
Gender	Male	100%		
Marital status	Married	100%		
Education	High school	100%		
Occupation	Teacher	100%		
Income	Low	100%		
Health status	Good	100%		
Smoking status	Non-smoker	100%		
Alcohol consumption	None	100%		
Stress level	Low	100%		
Sleep quality	Good	100%		
Physical activity	Low	100%		
Dietary habits	Healthy	100%		
Family size	Small	100%		
Workload	Low	100%		
Job satisfaction	High	100%		
Life satisfaction	High	100%		
Overall well-being	High	100%		

1. A device for securing a fold of tissue in a medical procedure, the

a first arm; and

a second arm disposed substantially opposite to the first arm and having an

2. The device of claim 1, wherein the first and second arms are

3. The device of claim 1, wherein at least one of the first and second

4. The device of claim 1, wherein at least one of the first and second

5. The device of claim 1, wherein a gripping tab is disposed on a free

6. The device of claim 1, wherein the first and second arms are comprised of a bioabsorbable material.

7. The device of claim 1, wherein the first and second arms form a substantially U-shaped configuration.

8. A method of securing a tissue fold in an endoluminal medical procedure, the method comprising the steps of:

- inserting an endoluminal device proximal to the tissue to be folded;
- folding tissue to create a tissue fold;
- inserting a tissue clip through the endoluminal device;
- positioning the tissue clip such that the tissue fold is placed in an opening defined by the clip; and
- engaging the fold with the tissue clip.

9. The method of claim 8, wherein the engaging step includes pulling upward on the clip.

10. The method of claim 8, wherein the engaging step includes frictionally engaging the clip with an outer surface of the tissue fold.

11. The method of claim 8, wherein the clip has first and second arms

60604550

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

defining a substantially U-shaped configuration and the engagement occurs between the arms and an outer surface of the tissue fold.

12. The method of claim 8, wherein the engaging step includes at least one barb disposed on the tissue clip engaging the tissue fold.

13. The method of claim 8, wherein the tissue clip inserting step includes gripping a gripping tab on a free end of the clip.

14. The method of claim 8, wherein the folding step includes folding a fundus wall onto and an esophagus wall.

15. A working end of an endoluminal device for use in an endoluminal medical procedure, the working end of the device comprising:

a plurality of interconnected members having an expandable working surface area configured to engage with a portion of the body to perform the medical procedure.

16. The device of claim 15, wherein the plurality of interconnected members includes a plurality of hydraulically-actuated members.

17. The device of claim 16, wherein each of said plurality of hydraulically-

009746030

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

actuated members defines a lumen, each said lumen being in fluid communication with each other.

18. The device of claim 17, wherein an area of the working surface changes in accordance with an amount of a hydraulic fluid supplied to the lumens.

19. The device of claim 17, wherein the hydraulically-actuated members engage each other in an end-to-end configuration when the lumens are filled with a hydraulic fluid.

20. The device of claim 17, wherein the hydraulically-actuated members substantially overlap each other when a hydraulic fluid is removed from the lumens.

21. The device of claim 18, wherein the hydraulically-actuated members include tubes.

22. The device of claim 21, wherein the tubes telescope as the area of the working surface is decreased.

23. The device of claim 15, wherein the interconnected members pivot relative to the endoluminal device to fold tissue during a fundoplication procedure.

20250754/5660

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-406-4000

actuated member.

30. The device of claim 29, wherein the member includes a plurality of hydraulically-actuated tubes.

31. The device of claim 30, wherein each of the plurality of tubes defines a lumen for receiving a hydraulic fluid, the lumens being in fluid communication with each other.

32. The device of claim 31, wherein the tube includes a passage in fluid communication with the tube lumens.

33. The device of claim 30, wherein the tubes have an end-to-end configuration when the arm is in the expanded configuration.

34. The device of claim 30, wherein the tubes are substantially concentrically disposed when the arm is in the retracted configuration.

35. A method for creating a tissue fold during an endoluminal medical procedure, the method comprising the steps of:

providing a tube and an expandable arm pivotably connected to a distal end of the tube;

inserting the tube into the body while the expandable arm is positioned along the tube and retracted;

pivoting the arm away from the tube;

expanding the arm;

positioning the arm adjacent the tissue to be folded; and

pivoting the arm toward the tube to fold the tissue.

36. The method of claim 35, wherein the expanding step includes expanding to an extent necessary to create a tissue fold of desired depth.

37. The method of claim 35, wherein the arm is expanded by hydraulic pressure.

38. The method of claim 35, wherein the arm includes a plurality of tubes having lumens in fluid communication with each other for receiving a hydraulic fluid, the arm expanding as the hydraulic fluid fills the lumens.

39. The method of claim 35, wherein the second pivoting step includes folding a fundus wall onto an esophagus wall.

40. The method of claim 35, further comprising the steps of:
inserting a tissue clip through the tube;

positioning the tissue clip such that the tissue fold is placed in an opening defined by the clip; and

engaging the fold with the tissue clip.

41. The method of claim 40, wherein the clip has first and second arms defining a substantially U-shaped configuration and the engagement occurs between the first and second arms and an outer surface of the tissue fold.

42. The method of claim 41, wherein the engaging step includes pulling upward on the clip.

43. The method of claim 42, wherein the engaging step includes frictionally engaging the clip with an outer surface of the tissue fold.

44. The method of claim 40, wherein the step of inserting the tissue clip includes feeding the clip out of the tube through a hole in a side of the tube over which the expandable arm is positioned during insertion of the tube into the body.

45. The method of claim 42, wherein the first arm of the clip is configured to be positioned between a first outer surface of the tissue fold and an outer surface of the tube and the second arm is configured to be positioned between a second

outer surface of the tissue fold and an inner surface of the expandable arm when the clip is being pulled upward.

46. The method of claim 40, wherein the expandable arm is retracted and the tube and expandable arm are removed from the body after the tissue clip is engaged to secure the tissue fold.

47. A device for securing a tissue fold, comprising:
a mounting member having a peripheral surface, the mounting member including a plurality of first engagement portions disposed about the peripheral surface; and

a plurality of tissue securing members configured to engage the mounting member at the first engagement portions and thereby secure a tissue fold.

48. The device of claim 47, wherein second engagement portions are disposed on each of the plurality of tissue securing members.

49. The device of claim 48, wherein the first engagement portions include one of engagement recesses and engagement members configured to engage the engagement recesses, and the second engagement portions include the other of the engagement recesses and the engagement members configured to engage the engagement recesses.

50. The device of claim 49, wherein the engagement recesses are apertures extending through the mounting member.

51. The device of claim 47, wherein the mounting member and the tissue securing members are configured to be inserted endoluminally to secure the tissue fold.

52. The device of claim 47, wherein the mounting member is made of relatively elastic material.

53. The device of claim 47, wherein the mounting member has a substantially circular shape.

54. The device of claim 47, wherein the peripheral surface of the mounting member defines an opening and the peripheral surface is configured to frictionally engage an inner surface of an esophagus.

55. The device of claim 47, wherein the mounting member and tissue securing members are made of a bioabsorbable material.

56. The device of claim 49, wherein each tissue securing member includes a first portion and a second portion connected to the first portion, wherein one of the first and second portions engages a first exterior surface of the tissue fold and the other of the first and second portions engages a second exterior surface of the tissue fold.

57. The device of claim 56, wherein each of the engagement members includes a shaft portion and a head portion, the head portion configured to pass through the engagement recess in a first direction prior to engagement and to be restricted from passing back through the engagement recess in a direction opposite to the first direction after engagement.

58. The device of claim 49, wherein the engagement members are configured to pierce tissue forming the tissue fold.

59. The device of claim 47, wherein the tissue securing members are integral with the mounting member.

60. The device of claim 47, wherein the tissue securing members are fixedly attached to the mounting member.

61. The device of claim 47, wherein the tissue securing members include

legs, each leg having one end attached to the mounting member and a free end.

62. The device of claim 61, wherein an engagement member is disposed proximate the free end of each leg, the engagement member being configured to engage the first engagement portions.

63. The device of claim 62, wherein the engagement member is rotatably mounted to the leg.

64. The device of claim 61, wherein each leg includes a hinge portion substantially at a midpoint of the leg.

65. A method for securing a tissue fold, comprising:
providing a mounting member having a peripheral surface and a plurality of first engagement portions disposed on the peripheral surface;

providing a plurality of tissue securing members adapted to engage the mounting member at the first engagement portions;

inserting the mounting member and tissue securing members endoluminally and proximal to the tissue fold to be secured;

positioning the tissue securing members on exterior surfaces of the tissue fold; and

engaging the tissue securing members with the first engagement portions to secure the tissue securing members in place with respect to the tissue fold and the mounting member.

66. The method of claim 65, wherein engaging the tissue securing members includes engaging a second engagement portion disposed on each of the tissue securing members with the first engagement portions.

67. The method of claim 65, wherein the engaging step includes piercing the tissue fold.

68. The method of claim 65, wherein the peripheral surface of the mounting member defines an opening and installing the mounting member includes frictionally engaging the peripheral surface of the mounting member with an inner surface of the esophagus.

69. The method of claim 65, wherein the tissue securing members include a first portion and a second portion connected to the first portion, and positioning the tissue securing members on exterior surfaces of the tissue fold includes positioning one of the first and second portions on a first exterior surface of the fold and the other of the first and second portions on a second exterior surface of the fold.

70. A device for securing tissue, comprising:

a tube defining a lumen therein and an opening proximate a distal end of the tube, said tube configured to accommodate suction through the lumen to draw tissue to be secured into the opening;

a holding member disposed in said lumen and configured to hold a tissue clip for securing the tissue; and

an inner member disposed in said lumen and configured to actuate relative to the tube between an open position and a closed position to open and close the tube opening, wherein the tissue clip is installed by the relative actuation.

71. The device of claim 70, wherein the inner member includes a sleeve, at least a portion of which has a semi-circular shape.

72. The device of claim 70, wherein the tube is configured for endoluminal insertion.

73. The device of claim 70, wherein the opening is in a side of the tube.

74. The device of claim 70, wherein the inner member disposed in said lumen includes a rotatable member, the rotatable member rotating to install the tissue clip.

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

75. The device of claim 70, wherein the holding member includes a first holding member disposed on the inner member.

76. The device of claim 75, wherein the holding member further includes a second holding member disposed on the tube.

77. The stapling device of claim 76, wherein the first holding member is configured to hold one of a female part and a male part and the second holding member is configured to hold the other of the female part and the male part, said female part and said male part being configured to engage each other to form said tissue clip.

78. The device of claim 77, wherein one of the first and second holding members holding the female part includes an aperture configured to align with an opening defined by the female part.

79. The device of claim 77, wherein the tube is configured to rotate in a direction opposite to a rotation of the inner member such that the first and second holding members move toward each other during installation of the tissue clip.

80. The device of claim 77, wherein the first holding member and

the second holding member are positioned at opposite sides of said tube opening when said inner member is in the open position.

81. The device of claim 77, wherein the second holding member includes a small lip disposed on an inner surface of the tube.

82. The device of claim 77, wherein the first holding member includes a small lip extending from an edge of the inner member.

83. The device of claim 77, wherein said female part defines a plurality of openings and the male part includes a plurality of darts configured to engage with said plurality of openings.

84. The device of claim 77, wherein the female part and the male part are made of a biocompatible material.

85. The device of claim 84, wherein the biocompatible material includes a bioabsorbable material.

86. A method of securing tissue together, comprising:
providing a tube defining a lumen therein and an opening proximate a distal end of the tube;

positioning said opening proximal to tissue to be secured together;
drawing tissue through said opening by the application of suction through
said lumen; and
actuating an inner member disposed in the lumen to install a tissue clip to
secure the tissue together.

87. The method of claim 86, wherein actuating the inner member
disposed in the lumen includes rotating the inner member relative to the tube to
install the tissue clip.

88. The method of claim 86, wherein said positioning includes inserting
the tube endoluminally.

89. The method of claim 86, wherein securing the tissue includes
securing esophageal tissue proximal the lower esophageal sphincter.

90. The method of claim 89, wherein securing the tissue includes
reducing the diameter of the esophagus.

91. The method of claim 86, further comprising holding the tissue clip in
said lumen prior to installing the tissue clip.

92. The method of claim 91, wherein the tissue clip is held in the lumen during the positioning and drawing steps.

93. The method of claim 92, wherein holding the tissue clip includes holding one of a female part and a male part by a first holding member on the tube and holding the other of the female part and male part by a second holding member on the inner member.

94. The method of claim 93, wherein the actuating step includes rotating the tube relative to the inner member to install the tissue clip such that the first holding member moves toward the second holding member.

95. The method of claim 87, wherein rotating the inner member includes rotating the inner member through an open position and a closed position to open and close the tube opening.

96. The method of claim 87, further comprising rotating the inner member to an original position and the stopping the suction after installation of the tissue clip.

97. The method of claim 96, further comprising rotating the tube opening

to a new position and repeating the drawing and actuating steps at the new position.

98. A device for securing tissue in a medical procedure, the device comprising:

a cannula having a proximal end, a distal end, and a longitudinal slot located adjacent the distal end;

a suction device for creating a vacuum through the cannula and to the slot, the suction urging tissue into the slot; and

a grasping element located in the cannula and movable between a non-grasping position where the element is outside a boundary of the slot to a grasping position where the grasping element is within the boundary of the slot.

99. The device of claim 98, wherein the grasping element is a wire extending from the slot and through the cannula to a proximal end portion of the device.

100. The device of claim 99, wherein the grasping element is a grasping plate.

101. The device of claim 100, wherein the grasping plate is formed in a C-shaped configuration.

102. A device for creating a tissue fold in an endoluminal medical procedure, the device including:

a tube defining a channel extending in a longitudinal direction from a proximal end to a distal end of the tube; and

an arm pivotably disposed on the distal end of the tube, said arm configured to pivot between a closed position substantially along the longitudinal direction and a position angled to the longitudinal direction.

103. The device of claim 102, wherein the angled position is substantially perpendicular to the longitudinal direction of the tube.

104. The device of claim 102, wherein the arm is substantially flush with the tube when it is in the position substantially along the longitudinal direction of the tube.

105. The device of claim 102, further including an actuator extending from the arm to the proximal end of the tube, wherein the actuator pivots the arm.

106. The device of claim 105, wherein the actuator includes a cable.

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

107. The device of claim 102, wherein the arm comprises an opening therethrough.

108. The device of claim 102, wherein the tube comprises a longitudinally extending slot at a distal end of the tube.

109. The device of claim 108, wherein the slot is located adjacent the arm when the arm is in the closed position.

110. The device of claim 102, wherein the tube includes a clear section at a distal end of the tube.

111. A method for creating a tissue fold during an endoluminal medical procedure, the method comprising the steps of:

providing a tube and an arm pivotably connected to a distal end of the tube;
inserting the tube into the body while the arm is positioned along the tube;
pivoting the arm away from the tube;
positioning the arm adjacent the tissue to be folded; and
pivoting the arm toward the tube to fold the tissue.

112. The method of claim 111, wherein the second pivoting step includes folding a fundus wall onto an esophagus wall.

113. The method of claim 108, further comprising the steps of:
inserting a tissue clip through the tube;
positioning the tissue clip such that the tissue fold is placed in an opening defined by the clip; and engaging the fold with the tissue clip.

114. The method of claim 113, wherein the clip has first and second arms defining a substantially U-shaped configuration and the engagement occurs between the first and second arms and an outer surface of the tissue fold.

115. The method of claim 114, wherein the engaging step includes pulling upward on the clip.

116. The method of claim 115, wherein the engaging step includes frictionally engaging the clip with an outer surface of the tissue fold.

117. The method of claim 113, wherein the step of inserting the tissue clip includes feeding the clip out of the tube through a slot in a side of the tube over which the arm is positioned during insertion of the tube into the body.

118. The method of claim 115, wherein the first arm of the clip is configured to be positioned between a first outer surface of the tissue fold and an outer surface of the tube and the second arm is configured to be positioned

between a second outer surface of the tissue fold and an inner surface of the arm when the clip is being pulled upward.

119. The method of claim 113, wherein the tube and arm are removed from the body after the tissue clip is engaged to secure the tissue fold.

0957431.093104
1012607645660

LAW OFFICES

INNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000